

In the Claims:

Please cancel claim 3.

Please amend claim 1 to read as follows:

AI 1. (Once Amended) A method of evaluating raw assay data that is arranged in a three dimensional array, the raw assay data being derived from an assay, the assay being subject to systematic and positional effects, the method comprising:

generating the raw assay data arranged in the three-dimensional array from a high throughput screening assay to identify a biologically active agent in a collection of test agents;

compensating the raw assay data for the systematic and positional effects;

scoring the compensated data;

formatting the scored data according to a determined format; and

identifying the biologically active agent by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data.

REMARKS

Claims 1, 2, and 4-58 are pending in the present application. Claims 10-58 have been withdrawn from further consideration as being directed to a non-elected invention. Claim 1 has been amended to include the subject matter of claim 3 in a positively recited manner, and claim 3 has therefore been canceled. Applicant respectfully submits that no new matter has been added to the application by the Amendment.

The Examiner has rejected claims 1, 2, and 4-9 under 35 U.S.C. §103(a) as being obvious over the TIGR Microarray Data Analysis System (MIDAS). Applicant respectfully traverses the first §103(a) rejection insofar as it may be applied to the claims as amended.

The Examiner has assigned a disclosure date to the TIGR MIDAS system of 1999, apparently based on such system being mentioned in a website showing a copyright date of 1999-2003. However, Applicant respectfully points out that the TIGR MIDAS system itself shows on an opening splash screen thereof a copyright date of 2001-2002 (page 2 of Microarray Software Training Manual). Thus, inasmuch as the present application was filed on August 4, 2000 and claims priority from a provisional application (60/217,772) filed on July 12, 2000, and inasmuch as the TIGR MIDAS system was disclosed 2001-2002, which is after July 12 and August 4, 2000, Applicant respectfully submits that the TIGR MIDAS system is unavailable as a prior art reference against the claims of the present application.

Accordingly, Applicant respectfully submits that the TIGR MIDAS system cannot be applied to make obvious claims 1, 2, and 4-9. As a result, Applicant respectfully requests reconsideration and withdrawal of the first §103(a) rejection.

The Examiner has also rejected claims 1, 2, and 4-9 under 35 U.S.C. §103(a) as being obvious over the S-PLUS statistical data analysis software as produced and/or marketed by MATHSOFT, Inc. of Cambridge, Massachusetts. Applicant respectfully traverses the second §103(a) rejection insofar as it may be applied to the claims as amended.

Independent claim 1 as amended recites a method of evaluating raw assay data that is arranged in a three dimensional array, where the raw assay data is derived from an assay and the assay is subject to systematic and positional effects. In the method, the raw assay data is generated from a high throughput screening assay to identify a biologically active agent in a collection of test agents, and the raw assay data is compensated for the systematic and positional effects. Thereafter, the compensated data is scored and formatted according to a determined format, and the biologically active agent is identified by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data.

As was set forth in the specification of the present application, the S-PLUS software is statistical data analysis software which may be employed to perform statistical analyses and manipulations on data. Thus, the S-PLUS software provides statistical functions that

may be employed in connection with the present invention. However, and significantly, the S-PLUS software does not disclose that any particular type of data be employed therewith, and in particular does not disclose or suggest that it be employed to compensate raw assay data for systematic and positional effects, as is required by claim 1. Moreover, the S-PLUS software is not at all concerned with generating the raw assay data from a high throughput screening assay to identify a biologically active agent in a collection of test agents, as is required by claim 1, nor is such S-PLUS software employable to generate such raw assay data.

In fact, the S-PLUS software is only employed to compensate the raw assay data, and such S-PLUS software is not otherwise used in connection with the present invention as recited in claim 1. In particular, such S-PLUS software does not and cannot score and format the compensated raw assay data, as is required by claim 1, nor can the S-PLUS software identify a biologically active agent by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data, as is required by claim 1. Instead, and typically although not necessarily, a human being or another computer process is required to perform such scoring, formatting, and identifying. Once again, the S-PLUS software only provides statistical functions that can be employed to compensate the raw assay data, but does not disclose or suggest that such statistical functions can or should be employed to evaluate raw assay data that is arranged in a three dimensional array, where the raw assay data is derived from an assay and the assay is

subject to systematic and positional effects, as with the present invention as recited in claim 1.

Accordingly, Applicant respectfully submits that the S-PLUS statistical data analysis software cannot be applied to make obvious claim 1 or any claims depending therefrom including claims 2 and 4-9. As a result, Applicant respectfully requests reconsideration and withdrawal of the second §103(a) rejection.

The Examiner has further rejected claims 1, 2, and 4-9 under 35 U.S.C. §103(a) as being obvious over the SCANALYZE system by Eisen. Applicant respectfully traverses the third §103(a) rejection insofar as it may be applied to the claims as amended.

The SCANALYZE system is a program for the analysis of DNA micro-array images, and in particular operates on fluorescent images from single or two-color fluorescent hybridizations and produces a table of results for subsequent analyses. However, and significantly, the SCANALYZE system is disclosed only in terms of 2-dimensional micro-array images, and therefore does not disclose or suggest evaluating raw assay data that is arranged in a three dimensional array, as is required by claim 1.

Moreover, the SCANALYZE system is not disclosed as being employed to compensate raw assay data for systematic and positional effects, as is required by claim 1. In fact, the SCANALYZE system does not appear to perform any statistical analyses at all. Instead, the SCANALYZE system is disclosed at page 4 as providing an interactive graphical environment for performing a locating process called gridding with regard to the

two-dimensional micro-array, and also extracts information on each gridded spot including fluorescence intensities, background intensities, fluorescence ratios and various quality control parameters.

Further, the SCANALYZE system in being directed to gridding and extracting information from an already-provided micro-array is not at all concerned with generating the raw assay data from a high throughput screening assay to identify a biologically active agent in a collection of test agents, as is required by claim 1, nor is such SCANALYZE system employable to generate such raw assay data. Further, such SCANALYZE system does not and cannot score and format the compensated raw assay data, as is required by claim 1, nor can the SCANALYZE system identify a biologically active agent by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data, as is required by claim 1.

Accordingly, Applicant respectfully submits that the SCANALYZE system cannot be applied to make obvious claim 1 or any claims depending therefrom including claims 2 and 4-9. As a result, Applicant respectfully requests reconsideration and withdrawal of the third §103(a) rejection.

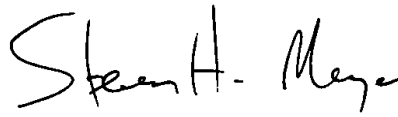
In view of the foregoing Amendment and Remarks, Applicant respectfully submits that the present application including claims 1, 2, and 4-9 is in condition for allowance, and such action is respectfully requested.

DOCKET NO.: MERK-0004

PATENT

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Steven H. Meyer". The signature is fluid and cursive, with the first name "Steven" and last name "Meyer" clearly distinguishable.

Steven H. Meyer
Registration No. 37,189

Date: April 29, 2003

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 3 has been cancelled.

Please amend claim 1 as follows:

1. (Once Amended) A method of evaluating raw assay data that is arranged in a three dimensional array, the raw assay data being derived from an assay, the assay being subject to systematic and positional effects, the method comprising:

generating the raw assay data arranged in the three-dimensional array from a high throughput screening assay to identify a biologically active agent in a collection of test agents;

compensating the raw assay data for the systematic and positional effects;

scoring the compensated data; [and]

formatting the scored data according to a determined format; and

identifying the biologically active agent by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data.